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12-12-02
PATENT
8086

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicants:	WOO, R.A., et al	:	Group Art Unit: 1623
Serial No.:	09/855,329	:	Examiner: Ganapathy Krishnan
Filing Date:	May 15, 2001	:	

For: **COMPOSITIONS COMPRISING CYCLODEXTRIN DERIVATIVES**

REQUEST FOR RECONSIDERATION

Box Non-Fee Amendment
Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

In response to the Office Action dated August 27, 2002, Applicants request reconsideration of the patentability of claims 1-16 in view of the following remarks.

REMARKS

The Official Action dated August 27, 2002 has been carefully considered. Accordingly, it is believed that the Substitute Declaration of Dean L. DuVal submitted herewith, taken with the following remarks, places this application in condition for allowance. Reconsideration is respectfully requested.

Defective Oath/Declaration

The oath or declaration was deemed defective for failure to comply with 37 C.F.R. §1.67(a). The Examiner asserts that the signature of one of the inventors, specifically Dean L. Duval, is missing. Enclosed herewith is a substitute Declaration signed and dated by Mr. DuVal. Applicants believe this substitute Declaration is in full compliance with the above code section, and that the objection has been overcome.

Double Patenting

Claims 1-10 and 12-15 were rejected under the doctrine of obviousness type double patenting as being unpatentable over claims 2-7 of U.S. Patent No. 5,942,217 (Woo '217), over claims 1 and 6-12 of U.S. Patent No. 5,997,759 (Trinh '759) and over claims 1-4 of U.S. Patent No. 6,436,442 (Woo '442). Specifically, the Examiner states that claims 1-10, while not identical to the Woo '217 and Trinh '759 patents, and claims 12-15, while not identical to claims 1-4 of Woo '442, are not patentably distinct because the claims of the instant application which are drawn to compositions or methods containing cyclodextrin (hereinafter CD) derivatives overlap with those of the cited patents. In particular, the Examiner asserts that the instant claims recite a specific average degree of substitution for the CDs whereas the prior art recites a broad range for the degree of substitution.

This rejection is traversed and reconsideration is respectfully requested. Applicants concede that the instantly claimed compositions include CDs within the scope of the CDs recited in the Woo '217 and Trinh '759 Patent claims. However, there are differences between the subject matter presently claimed and the references' claims such that the instant claims are patentably distinct and, hence, the obviousness type double patenting rejections are improper.

It is axiomatic that a later invention may be patented even though the earlier patent has a broad claim which encompasses an invention defined by the later more specific claim. [W]e hold that a species claim is not necessarily obvious in light of a prior art disclosure of a genus." *In re Sarett*, 327 F.2d 1005, 1013, 140 USPQ 174, 481 (CCPA 1964). *In re Baird*, 16 F.3d 380, 29 USPQ 2d. 1550 (Fed. Cir. 1994), and *In re Jones*, 958 F.2d 347, 21 USPQ 2d. 1941 (Fed. Cir. 1992). The purpose of the double patenting doctrine is to prevent a patent term extension through claims in a second patent that are not patentably distinct from those in the first patent. Hence, the second invention is patentable, even if the claimed subject matter is wholly within that claimed by the first, if it complies with the requirements for patentability found in the statute, namely, novelty, utility and nonobviousness. The proper inquiry is "whether the claimed invention in the application for the second patent would have been obvious from the subject matter of the claims in the first patent, in light of the prior art. *Carmen Industries Inc. v. Wahl*, 724 F.2d 932,940 220 USPQ 481,487 (Fed. Cir.1983).

Applicants submit that the unexpectedly enhanced efficacy (as disclosed in the present specification, at page 6, lines 16-20 and in Example 1) of the presently claimed

compositions comprising CDs having a low average degree of substitution, is neither predictable nor obvious to one skilled in the art in light of the broadly claimed CDs of Woo '217 and Trinh '759. Applicants find no teaching in the cited references' claims suggesting that the presently claimed CDs have or might be of special interest or yield a superior result to those broadly claimed by Woo '217 and Trinh '759. The Examiner cites no basis, nor do the references provide a basis for any expectation by those skilled in the art for the superior results engendered by the instantly claimed compositions. In order for an obviousness-type double patenting rejection to be sustained, "there must be some clear evidence to establish why the variation would have been obvious which can properly qualify as 'prior art'". *Id.* Note that in considering the question, the patent specification itself may not be used as prior art. *In re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968).

Hence, Applicants submit that the instant invention is patentably distinct from the claims of the Woo '217 and Trinh '759 patents.

With respect to claims 12-15 of the instant application, the Examiner asserts that the only difference in the instant claims from claims 1-4 of the Woo '442 patent is that the instant claims recite CD-compatible and incompatible "surfactants," whereas the Woo '442 patent recites CD-compatible and incompatible "materials." The Examiner also notes that the Woo '442 patent and the instant claims 12-15 are drawn to analogous processes of manufacturing compositions with otherwise completely overlapping limitations. Applicants, however, note that the inventive method of present independent claim 12 employs the novel, nonobvious low-degree of substitution CDs, which are patentably distinct from the broadly defined CDs of the Woo '442 patent claims. Hence, when taken as a whole, the process of the present invention is patentably distinct from that of the Woo '442 claims.

Therefore, Applicants submit that the double patenting rejections of claims 1-10 and 12-15 have been overcome. Reconsideration is respectfully requested.

35 U.S.C. §112

Claims 1, 2, 5, 6, 11, 12, and 16 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Specifically, the Examiner asserts that the term "low-degree" is a relative term, not "defined by the claim", and that one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The rejection is traversed and reconsideration is respectfully requested. Applicants submit that the phrase "low-degree" is clearly defined in the specification such that one of ordinary skill in the art is apprised of the scope of the claim. That is, comparative words are indefinite unless those words have been clearly defined in the disclosure or specification and/or the basis of the comparison, what is being compared, is stated and/or one of ordinary skill in the art, in view of the prior art and the status of the art, would be apprised of the scope of the claim. See MPEP 2173.05(b). The critical determination, then, is whether those skilled in the art would understand what is claimed when the claim is read in light of the specification. At page 6, lines 12-15, the present specification succinctly defines the term "low-degree of substitution" to refer to CDs "in which less than about one-fourth (1/4) of the OH groups of the CD molecule have been converted to OR groups." Since the number of OH groups varies per CD type, what is meant by "low-degree" cannot be more precisely defined.

"If the claims, read with the specification, reasonably apprise those skilled in the art of both the utilization and the scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more." *Miles Labs, Inc. v. Shandon, Inc.*, 997 F.2d 870, 27 USPQ 2d 1123 (Fed.Cir.1993). Hence, the claim as written is not indefinite since the term "low-degree of substitution" is defined as precisely as reasonably possible in the present specification. Therefore, the rejections of claims 1, 2, 5, 6, 11, 12, and dependent claim 16, have been overcome and reconsideration is respectfully requested.

35 U.S.C. § 103

Claims 1-10 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,997,759 (Trinh '759) in combination with U.S. Patent No. 5,578,563 (Trinh '563) and U.S. Patent No. 5,942,217 (Woo '217). Specifically, the Examiner asserts that the difference between the instant claims and the references is that the instant claims recite a specific average degree of CD substitution whereas the references disclose a broader range for CD degree of substitution. Additionally, the Examiner asserts that the degree of substitution of the hydroxyalkyl and alkyl cyclodextrins used in the instant composition all fall within the range disclosed in the cited prior art. The Examiner thus asserts that it would have been obvious to combine Trinh '563, Trinh '759 and Woo '217 to make cyclodextrin compositions with the average degree of substitution as instantly claimed, and that the motivation for doing so is "because it can be used as the base composition to which various

other ingredients can be added to prepare new compositions for unique sanitizing and cleansing purposes."

This rejection is traversed and reconsideration is respectfully requested. According to claim 1, the invention is directed to compositions for capturing unwanted molecules and comprising low-degree of substitution cyclodextrin derivative. Applicants submit that the compositions comprising low degree substitution cyclodextrins engenders an enhanced efficacy such that the compositions are patentably distinct from those of random-degree substitutions as taught in the cited prior art. Trinh '563, Trinh '759, and Woo '217 all broadly teach the use of derivatized cyclodextrin compositions wherein the degree of substitution of alkylated derivatives is in the range of from about 3 to about 16 (Woo '217, col.7, lines 49-52, Trinh '563 col.10, lines 64-66, and Trinh '759 col.8, lines 64-66) and the degree of substitution recited for hydroxyalkyl derivatives is from about 1.5 to about 7 (Woo '217, col.7, lines 45-48, Trinh '563, col.10, lines 60-62, and Trinh '759, col.8, lines 60-63). The present invention, on the other hand, requires low degree of substitution CD derivative. Applicants submit that the selection of low degree of substitution cyclodextrins in the present invention is a nonobvious over the prior art and is therefore patentably distinct.

It is well settled that the question of obviousness under 35 U.S.C. §103 is not what the person skilled in the art could have done but rather what would have been obvious for such a person to do. *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 1 U.S.P.Q.2d 1081 (Fed. Cir. 1986). One skilled in the art would first have to appreciate that such a selection of a CD as required by the present claims would confer the unexpected efficacy taught in the present disclosure. Absent reference to the present disclosure, there is no motivation to create such compositions. There is no suggestion in any of the cited references, nor is it apparent from knowledge of the state of the art, to select from the derivatized cyclodextrins broadly disclosed in the references to obtain compositions comprising the low-degree substitution cyclodextrins required by the present claims.

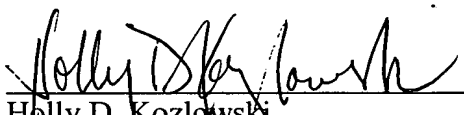
There is no motivation to combine the cited references without the hindsight afforded by the disclosure of unexpected efficacy of the specific cyclodextrins required in the compositions of the present invention. The Examiner would have to employ Applicants' own teaching to provide the motivation to combine the cited prior art. It is impermissible to use the claims as a frame and the prior art references as a mosaic to piece together a facsimile of the claimed invention. *Uniroyal,* 837 F.2d at 1051, citing *W.L. Gore & Assocs., Inc. v.*

Garlock, Inc., 721 F.2d 1540, 1551 [220 USPQ 303] (Fed. Cir. 1983), *cert. denied,* 469 U.S. 851 (1984).

Thus, one of ordinary skill in the art would not find it obvious to combine the teachings of Trinh, Trinh and Woo to yield the present invention. Hence, the rejection has been overcome and reconsideration is respectfully requested.

It is believed that the above represents a complete response to Examiner's rejections under 35 U.S.C. §§ 112, second paragraph and 103, and on the basis of obviousness-type double patenting, and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,

By: 

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CERTIFICATE OF MAILING

I hereby certify that this paper is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Box Non-Fee Amendment; Commissioner for Patents, Washington, DC 20231 on November 27, 2002.

Lynne W. Moore

Lynne W. Moore

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicants:	WOO, R.A., et al	:	Paper No:	
Serial No.:	09/855,329	:	Group Art Unit:	1623
Filed:	May 15, 2001	:	Examiner:	Ganapathy Krishnan

For: **COMPOSITIONS COMPRISING CYCLODEXTRIN DERIVATIVES**

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Commissioner for Patents
Washington, DC 20231

Dear Sir:

Transmitted herewith is a Request for Reconsideration in the above-identified application.

[X] Also attached: Substitute Declaration of Dean L. DuVal and Return Receipt Postcard.

The fee has been calculated as shown below:

	NO. OF CLAIMS	HIGHEST PREVIOUS PAID FOR	EXTRA CLAIMS	RATE	FEE
Total Claims	16	20	0	x $18 =	$----
Independent Claims	3	3	0	x $84 =	$----
		TOTAL FEE DUE			$----

[X] The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication or credit any overpayment, to Deposit Account No. 04-1133, including any filing fees under 37 CFR 1.16 for presentation of extra claims and any patent application processing fees under 37 CFR 1.17.

Respectfully submitted,

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Date: November 27, 2002

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